

In the United States Court of Federal Claims

No. 99-524V

(Filed Under Seal: October 26, 2011)

(Reissued: November 10, 2011)¹

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THOMAS WALTER RICCI, a minor, through his
parents and natural guardians, DANIEL RICCI
and EVA RICCI,

Petitioners,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Review of Special Master's
Vaccine Act Decision; Alleged
Seizure Disorder Caused by
Hepatitis B Vaccine; Petitioners'
Failure to Establish Evidence of
Inflammation; Court's Deference
to Special Master's Reasonable
Review of Evidence.

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Michael P. Milmo, with whom were *Tony West*, Assistant Attorney General, *Mark W. Rogers*, Acting Director, *Vincent J. Matanoski*, Acting Deputy Director, and *Gabrielle M. Fielding*, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for Respondent.

OPINION AND ORDER

WHEELER, Judge.

This case comes before the Court on review of Special Master Christian J. Moran's May 16, 2011 decision denying compensation to Petitioner, Thomas Ricci, through his parents, Daniel and Eva Ricci, under the National Childhood Vaccine Injury

¹ This opinion originally was issued under seal on October 26, 2011. Pursuant to Rule 18(b) of the Vaccine Rules of the United States Court of Federal Claims ("Vaccine Rules"), the parties had 14 days within which to propose redactions to the opinion prior to its publication, but no such redactions were proposed. Accordingly, the opinion is herein reissued for publication, unsealed.

Act (“Vaccine Act”), 42 U.S.C. §§ 300aa-2 - 33 (2006). Petitioners allege that the Hepatitis B vaccine Thomas received on October 8, 1992 resulted in an adverse reaction, which caused “an encephalopathy and/or encephalitis and/or meningoencephalitis . . . and that this injury has left Thomas with a residual seizure disorder” impairing his cognitive and physical development. Pet’rs Br. 1-2, Nov. 12, 2010. Respondent contends Petitioners are not entitled to recover because they failed to prove a necessary link in the causal chain, namely that the administered vaccine caused inflammation in Thomas’s central nervous system. See Resp’t Resp. 8-11, Jul. 14, 2011.

The special master agreed with Respondent, finding neither the relevant medical tests nor Thomas’s clinical presentation proved, by preponderant evidence, that Thomas suffered inflammation at the time his seizures commenced. See Ricci v. Sec’y of Health & Human Servs., 2011 WL 2260391, at *6-12 (Fed. Cl. May 16, 2011). For the reasons stated below, the Court AFFIRMS the special master’s decision and DENIES Petitioners’ motion for review.

Background

A. Statement of Facts

Thomas Ricci was born to Daniel and Eva Ricci on July 8, 1992, weighing eight pounds and fifteen ounces. Pet’rs Mot. Rev. 3, Jun. 14, 2011. He was born “without complications or problems . . . following a normal pregnancy, labor, and delivery.” Id. In subsequent weeks, Thomas “was in good health, developing normally, was attentive, and gave no indications whatever of any kind of abnormality.” Id.

On October 8, 1992, Thomas received a vaccination for Hepatitis B at the office of Dr. Ofelia B. Ayuste, his pediatrician. Id. On October 13, 1992, Thomas’s mother, Eva Ricci, noticed his arm jerk. E. Ricci, Tr. 10. Mrs. Ricci reported the incident to a colleague of Dr. Ayuste, who instructed her to make an appointment when Dr. Ayuste returned from a vacation. Pet’rs Mot. Rev. 4, Jun. 14, 2011. During an appointment on October 15, 1992, Dr. Ayuste witnessed Thomas’s arm jerk again and immediately instructed Mrs. Ricci to take him to Adventist Hinsdale Hospital, Illinois. Id.; E. Ricci, Tr. 12 (“[Dr. Ayuste] was very upset, visibly upset, and I was very frightened because she said he was having a seizure and I needed to go directly to the hospital.”).

Thomas was hospitalized from October 15 through October 21, 1992. Pet’rs Mot. Rev. 4, Jun. 14, 2011. He underwent multiple tests—cerebrospinal fluid, genetic, computed tomography (“CT”) scan with contrast, magnetic resonance imaging (“MRI”), and electroencephalogram (“EEG”) study—but doctors were unable to identify a cause of his symptoms, such as inflammation. See Pet’rs Ex. 3, at 96, 102-03, 113, 116-17, 129. Ultimately, doctors diagnosed Thomas with “[i]nfantile seizure disorder of undetermined

etiology” and discharged him with prescriptions for Amoxicillin, Pyridoxine, and Phenobarbital, the latter to control his seizures. Id. at 92-94.

Despite the medication, Thomas shortly developed break-through seizures. Pet’rs Mot. Rev. 4, Jun. 14, 2011. On November 6, 1992, he was admitted to Loyola University Medical Center to undergo additional testing. See Pet’rs Ex. 4, at 3-7, 12, 15, 20-21. All tests to identify the cause of Thomas’s seizures were inconclusive. Pet’rs Mot. Rev. 4, Jun. 14, 2011.

Thomas continues to have seizures to this day. Id. at 5. His “cognitive and physical development was effectively terminated at the age of three months,” his age when the seizures commenced. E. Ricci, Tr. 7. In June 2011, at the age of eighteen, Thomas “is five feet, seven inches tall, weighs less than 100 pounds, has the cognitive abilities of a three to six month old baby, has visual tracking and language levels of a three month old, and is physically unable to bear his own weight.” Pet’rs Mot. Rev. 5, Jun. 14, 2011.

The Hepatitis B vaccine is listed on the “Vaccine Injury Table,” but Thomas’s alleged injury is not covered. See 42 U.S.C. § 300aa-14 (2006); 42 C.F.R. § 100.3 (2011).

B. History of Proceedings

Petitioners filed their Vaccine Act petition in this Court on July 28, 1999, alleging that the Hepatitis B vaccine, which Thomas had received on October 8, 1992, caused his seizure disorder. Ricci, 2011 WL 2260391, at *2. The Office of Special Masters (“OSM”) “informally stayed” the matter, as the parties in many other similar cases attempted to structure a mass settlement, which was “not entirely successful.” Id. In 2006, the OSM assigned the matter to Special Master Moran for independent review. Id.

1. Expert Witness Reports

At first, Petitioners did not file any expert witness reports with their 1999 petition. See id. However, upon the matter’s assignment to the special master in 2006, Respondent filed a report, pursuant to Rule 4 of the Court’s Vaccine Rules (found in Appendix B), maintaining that Petitioners were not entitled to compensation for failure to offer an expert in support of their claim. Id.; see also Resp’t Report 4, Feb. 1, 2007. In response, on August 3, 2007, Petitioners filed the curriculum vitae and report of Dr. Lawrence Steinman. Ricci, 2011 WL 2260391, at *2; see also Pet’rs Exs. 9-24.

a. Petitioners' Expert, Dr. Lawrence Steinman

Dr. Steinman is a full professor of genetics, neurology, and pediatrics at Stanford University. Pet'rs Mot. Rev. 6, Jun. 14, 2011. He is Chair of the institution's "Program in Immunology." Id. Dr. Steinman is board-certified in neurology, has authored more than 400 articles, holds editorial positions on immunology and neurology journals, holds many patents relating to autoimmune conditions, and "has won many prestigious awards." Id. at 6-7.

Upon reviewing Thomas's medical records, Dr. Steinman concluded that Thomas experienced "neurological damage from his immunization with recombinant Hepatitis B on October 13, 1992" and "a post-immunization encephalopathy, with evidence of a mild meningoencephalitis . . . on [October] 15." Pet'rs Ex. 9, at 2. He proposes that Thomas developed seizures because of an autoimmune process known as "molecular mimicry," whereby the body confuses an antigen (foreign substance) with its own tissue and "[i]n the process of responding to [the] antigen, the body's immune system becomes confused and attacks its own tissue." Ricci, 2011 WL 2260391, at *5. In essence, because of similarities between the Hepatitis B virus and the myelin (white matter) that sheaths Thomas's neural cells, the vaccine "elicited an immune response that [led] to neurological damage." Pet'rs Ex. 9, at 3. Dr. Steinman's theory is contingent upon the presence of meningoencephalitis, inflammation of the brain and meninges (membranes), at the onset of Thomas's seizures. Steinman, Tr. 37, 345-46; see also Ricci, 2011 WL 2260391, at *4 ("[T]his immune response would be manifest as inflammation.").

According to Dr. Steinman, heightened levels of white blood cells and protein in Thomas's cerebrospinal fluid, at the time his symptoms presented, were indicative of inflammation in a child of his age. Steinman, Tr. 62-63, 340. Dr. Steinman also postulated that Thomas's thin corpus callosum (tissue connecting the two sides of the brain), as evidenced by MRI imaging eleven days after vaccination (October 19, 1992), suggested brain atrophy. Id. at 62, 331; see also Pet'rs Ex. 3, at 117.

b. Respondent's Expert, Dr. Max Wiznitzer

Respondent offered Dr. Max Wiznitzer as its expert. Ricci, 2011 WL 2260391, at *3; see also Resp't Exs. A-B. Dr. Wiznitzer is an associate professor of international health, neurology, and pediatrics at Case Western Reserve University. Ricci, 2011 WL 2260391, at *3; Wiznitzer, Tr. 123. He is board certified in neurology, neurodevelopmental disabilities, and pediatrics, with a special competence in child neurology and a focus in autism, developmental disabilities, and epilepsy. Ricci, 2011 WL 2260391, at *3 (internal citation omitted); Wiznitzer, Tr. 119-20. Dr. Wiznitzer has authored approximately 50 articles in peer-reviewed journals. Ricci, 2011 WL 2260391, at *3.

In Dr. Wiznitzer's opinion, "[t]here is no evidence of an encephalopathy [disease of the brain] with associated meningoencephalitis [inflammation] at the time of [Thomas's] hospital admission" on October 15, 1992. Resp't Ex. A, at 3. Dr. Wiznitzer bases his conclusion on three considerations: (1) to his knowledge, there is no evidence an infant can develop a seizure disorder in reaction to the Hepatitis B vaccine; (2) he contends that Dr. Steinman's molecular mimicry theory, as applied to Thomas's seizure disorder, is not biologically plausible; and (3) he believes it is improper to review approximately twenty year-old medical records to impose a diagnosis when the original tests failed to indicate the diagnosis. Wiznitzer, Tr. 165; see also id. at 150 ("[T]he only thing that we have is . . . a temporal association between the vaccine and the onset of the seizure disorder."). Importantly, Dr. Wiznitzer determined that Thomas did "not meet clinical criteria . . . for meningoencephalitis." Id. at 203.

According to Dr. Wiznitzer, the heightened white blood cell and protein levels in Thomas's cerebrospinal fluid were within normal parameters and, thus, not indicative of inflammation. Id. at 202-04 (explaining that Thomas's levels were "normal" within the ranges used by multiple hospitals and "a large committee that had nothing to do with any of this legal action"). Dr. Wiznitzer also explained that the radiologist who interpreted the October 19, 1992 MRI, which evidenced a thin corpus callosum, may have "overinterpreted," as three additional MRIs, conducted in 1993 and 1994, evidenced a corpus callosum of "normal" thickness. Id. at 180-82.

2. Evidentiary Hearings

The special master conducted two evidentiary hearings in this matter. See Ricci, 2011 WL 2260391, at *3-4. The first occurred on May 11, 2009, in which Mrs. Ricci and Dr. Steinman testified. Id. at 3. At a second hearing on December 14 and 15, 2009, both Dr. Steinman and Dr. Wiznitzer testified. Id. at 4. In between the two hearings, the parties filed medical articles, additional medical records, and supplemental expert reports. Id.

During the second hearing, on December 14, 2009, Dr. Wiznitzer indicated that he occasionally sees patients while travelling out of state, prompting Petitioners' counsel to proffer that Dr. Wiznitzer may have committed a crime by violating state physician licensing requirements. See Wiznitzer, Tr. 219-22. That sequence of events triggered a motion in limine by Respondent, multiple status conferences, and the submission of briefs concerning the overall appropriateness of Dr. Wiznitzer's testimony in this matter. Ricci, 2011 WL 2260391, at *4; Pet'rs Reply 6-7, May 18, 2010 ("Whether a physician practices medicine in a state where he is not licensed . . . bears directly on his character for truthfulness or untruthfulness."). Ultimately, the special master granted in part and denied in part Respondent's motion to exclude Dr. Wiznitzer's testimony concerning his out of state medical practice. See Order, at 7, Aug. 13, 2010 (denying the exclusion of

testimony but precluding any additional questioning on the issue); Resp't Mot. In Limine, Apr. 15, 2010.

3. The Special Master's Decision

On May 16, 2011, the special master issued his decision denying Petitioners compensation. See Ricci, 2011 WL 2260391. The special master concluded, "dispositive evidence shows that Thomas did not react in a way posited by Dr. Steinman's theory." Id. at 1. In other words, because the special master determined that preponderant evidence does not indicate the presence of meningoencephalitis at the time Thomas's seizures began, there is a break in the causal chain which links the Hepatitis B vaccine to Thomas's condition. Id. at 12 (internal footnote omitted).

Petitioners moved for review of the special master's decision on June 14, 2011. Respondent filed a response on July 14, 2011, asking the Court to affirm the decision. The Court heard oral argument on September 21, 2011.

Standard of Review in Vaccine Act Cases

In a case arising under the Vaccine Act, the Court reviews the decision of the special master "to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.'" Markovich v. Sec'y of Health & Human Servs., 477 F.3d 1353, 1355-56 (Fed. Cir. 2007) (citing 42 U.S.C. § 300aa-12(e)(2)(B) (2006)). The Court is "highly deferential" to a special master's findings of fact. Masias v. Sec'y of Health & Human Servs., 634 F.3d 1283, 1287 (Fed. Cir. 2011). Accordingly, "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991). Ultimately, "it is not [] the role of this [C]ourt" to "examine the probative value of the evidence or the credibility of the witnesses." Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 871 (Fed. Cir. 1992). In contrast, the Court "owe[s] no deference to [] the special master . . . on questions of law." Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005) (internal citation omitted). The Court reviews applications of law de novo. Masias, 634 F.3d at 1288.

Standard of Causation in Vaccine Act Cases

Congress established two ways for a petitioner to prove causation under the Vaccine Act. Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The first occurs when the petitioner received a vaccine that appears on the Vaccine Injury Table and, within a prescribed time period, suffered an injury listed in the Table for the vaccine. Id. (citing 42 U.S.C. § 300aa-14 (2006)); see also 42 C.F.R. § 100.3 (2011). There, the Court presumes causation, and the respondent bears the burden

of proving that the actual cause of injury was a factor unrelated to the vaccine. Pafford, 451 F.3d at 1355 (citing 42 U.S.C. § 300aa-13(a)(1) (2006)).

In contrast, when the petitioner suffers an “off-table” injury, the petitioner bears the burden of proving the vaccine’s “causation-in-fact.” Pafford, 451 F.3d at 1355 (citing 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I), -13(a)(1) (2006)). The Federal Circuit has defined this burden as follows:

[Petitioner]’s burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen, 418 F.3d at 1278.

A petitioner who satisfies the three prongs of Althen establishes a prima facie case, “absent proof that some other factor was the actual cause.” de Bazan v. Sec’y of Health & Human Servs., 539 F.3d 1347, 1354 (Fed. Cir. 2008) (emphasis omitted). If the respondent, however, presents evidence of an alternative cause “to demonstrate the inadequacy of the petitioner’s evidence on a requisite element,” de Bazan, 539 F.3d at 1353, the special master may “consider such evidence in deciding whether [the petitioner] established a prima facie case,” Doe v. Sec’y of Health & Human Servs., 601 F.3d 1349, 1351, 1358 (Fed. Cir. 2010).

Once a petitioner establishes a prima facie case, the burden shifts to the respondent to demonstrate by preponderant evidence that “factors unrelated to the administration of the vaccine” in fact caused the injury. Broekelschen v. Sec’y of Health & Human Servs. (“Broekelschen I”), 89 Fed. Cl. 336, 343 (2009), aff’d, 618 F.3d 1339 (Fed. Cir. 2010) (internal citation omitted). Unrelated factors may include “infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relationship to the vaccine involved,” but may not include “any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness or condition.” 42 U.S.C. § 300aa-13(a)(2) (2006).

Discussion

Petitioners challenge Special Master Moran’s decision to deny compensation on three grounds: (1) for relying on Thomas’s contemporaneous medical records at the expense of Dr. Steinman’s present testimony; (2) for assigning greater weight to Dr. Wiznitzer’s testimony concerning inflammation than to Dr. Steinman’s testimony concerning molecular mimicry; and (3) for allowing Dr. Wiznitzer to testify about

immunological issues. The Court addresses each of these grounds in turn and ultimately concludes that Petitioners cannot justify disturbing the special master's decision.

A. The Special Master Was Correct to Rely on Thomas's Contemporaneous Medical Records at the Expense of Dr. Steinman's Present Testimony.

Petitioners contend that the special master unduly relied on the absence of notes in Thomas's medical records at the time his symptoms first presented, which would have linked the vaccine to his seizures and other injuries. Pet'rs Mot. Rev. 18, Jun. 14, 2011. This contention is not persuasive. Where present-day testimony conflicts with contemporaneous documentary evidence, the former deserves minimal weight. Montgomery Coca-Cola Bottling Co., Inc. v. United States, 222 Ct. Cl. 356, 615 F.2d 1318, 1328 (1980) (discussing United States v. United States Gypsum Co., 333 U.S. 364, 396 (1947)). Contemporaneous medical records "warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium." Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). Moreover, statements by treating physicians are entitled to significant weight in Vaccine Act cases. Campbell v. Sec'y of Health & Human Servs., 90 Fed. Cl. 369, 386 (2009).

Here, Petitioners "concede that Thomas's treating physicians in October 1992 did not link his vaccination with his injury." Pet'rs Mot. Rev. 19, Jun. 14, 2011. Likewise, Thomas's treating physicians did not diagnose him as having inflammation, a necessary condition for molecular mimicry to apply. Ricci, 2011 WL 2260391, at *11 (summarizing Thomas's medical records in chart form). Dr. Steinman's testimony—explaining causation with a molecular mimicry theory that requires inflammation and explaining inflammation with an ex-post facto interpretation of contemporaneous evidence to the contrary, see Steinman, Tr. 300, 329-30—is not sufficient under Montgomery Coca-Cola. While it is possible a treating physician in 1992 might not have had the frame of reference to document a molecular mimicry diagnosis, that physician certainly would have been on the lookout for brain inflammation in a baby experiencing a sudden bout of seizures. The absence of such a diagnosis is highly probative.

Additionally, Petitioners note that some of Thomas's later treating physicians did link his vaccination with his seizures. See Pet'rs Mot. Rev. 19-20, Jun. 14, 2011 (collecting quotes from those physicians). They argue that those physicians' observations "have significant probative value." Id. at 20. Those observations, however, were not contemporaneous. Medical records from years later, merely chronicling a timeline between vaccination and injury, are not worthy of the same consideration as contemporaneous records. Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1348 (Fed. Cir. 2010); see also Ricci, 2011 WL 2260391, at *2 n.2 (observing that,

besides Dr. Steinman, none of Thomas's physicians between 1992 and the present have attributed his seizure disorder directly to the vaccine).

B. The Special Master Was Correct to Assign Greater Weight to Dr. Wiznitzer's Testimony Concerning Inflammation than to Dr. Steinman's Testimony Concerning Molecular Mimicry.

Petitioners dispute the special master's assignment of greater weight to the testimony of Dr. Wiznitzer than to the testimony of Dr. Steinman, on the plausibility of Dr. Steinman's molecular mimicry theory as the cause of Thomas's seizure disorder. Pet'rs Mot. Rev. 10, Jun. 14, 2011. They reason that, by doing so, the special master improperly short-circuited his Althen analysis. Id. at 17-18.

In their motion for review, Petitioners refer the Court to Campbell, 90 Fed. Cl. at 382-84 (Lettow, J.), and Rotoli v. Secretary of Health and Human Services, 89 Fed. Cl. 71, 80-82 (2009) (Firestone, J.), in which petitioners prevailed upon the Court's application of Andreu v. Secretary of Health and Human Services, 569 F.3d 1367 (Fed. Cir. 2009), which governs a special master's determination of witness credibility.² While the Court finds Campbell and Rotoli to be well reasoned and persuasive, the issue here is not the credibility of Dr. Steinman but whether the inflammation necessary for his theory to apply was present. Without inflammation, molecular mimicry simply is not plausible as an explanation for Thomas's seizure disorder.

Where "nearly all of the evidence on causation" is dependent on the diagnosis of a particular injury, it is "appropriate for the special master to first find which of [the] diagnoses [is] best supported by the evidence presented in the record before applying the Althen test." Broekelschen v. Sec'y of Health & Human Servs. ("Broekelschen II"), 618 F.3d at 1346. In other words, "identifying the injury is a prerequisite to" Althen analysis. Id.

² Both Campbell and Rotoli involved the same special master as the instant case. See Campbell, 90 Fed. Cl. at 384 n.29. According to the Andreu panel:

While considerable deference must be accorded to the credibility determinations of special masters . . . this does not mean that a special master can cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review. A trial court makes a credibility determination in order to assess the candor of a fact witness, not to evaluate whether an expert witness' medical theory is supported by the weight of epidemiological evidence.

569 F.3d at 1379.

Petitioners aver that despite Dr. Wiznitzer's qualifications to identify or diagnose inflammation, he "does not possess the expertise, credentials, knowledge, or experience to explain or appreciate the immunologically mediated process" (molecular mimicry), which they allege caused Thomas's inflammation. Pet'rs Mot. Rev. 12, Jun. 14, 2011. Petitioners posit that, in contrast, "Dr. Steinman carefully pointed out each and every aspect of the [causation] theory, as well as provided biological support for the theory with pertinent medical literature." *Id.* at 10-11. They further argue, the "logical sequence of cause and effect showing that the vaccination was the reason for the injury are directly associated with immunological and autoimmune phenomena that only Dr. Steinman has the qualifications to adduce and explain." *Id.* at 11 (internal quotation omitted).

Nevertheless, the Court agrees with Respondent that this ground for challenging the special master's decision is "irrelevant" and "moot." Resp't Resp. 6, 8, Jul. 14, 2011. After all, the special master had "assume[d] that Dr. Steinman's theory is persuasive." *Id.* at 6 (quoting *Ricci*, 2011 WL 2260391, at *6 n.5). Since the special master "rationally concluded that a determination about Dr. Steinman's theory [*Althen* prong one] was not necessary . . . because factual support . . . was lacking" due to the absence of "direct or circumstantial evidence" of inflammation, there was no need for him to proceed to evaluate the validity of the theory (*Althen* prong two). *Id.* at 6-7. Indeed, without inflammation, "the special master would have been obliged to disregard Dr. Steinman's theory as being inherently unreliable, even had Dr. Wiznitzer never testified." *Id.* at 7 (internal footnote omitted).

C. The Special Master Properly Allowed Dr. Wiznitzer to Testify About Only the Manifestations of Immunological Issues, Not Their Underlying Bases.

In their motion for review, Petitioners refer the Court to *Terran v. Secretary of Health and Human Services*, 195 F.3d 1302 (Fed. Cir. 1999), in which an appellate panel held that a special master may use the factors from *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), as a "tool for analyzing the admissibility of scientific testimony." *Terran*, 195 F.3d at 1316 (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999)).³ Here, Petitioners contend that Dr. Wiznitzer lacked a reliable basis, in satisfaction of *Daubert*, "to testify on the dispositive immunological issues of the case." Pet'rs Mot. Rev. 9, Jun. 14, 2011. Specifically,

³ The *Daubert* factors to measure the reliability of expert testimony are:

- (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and, (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (discussing *Daubert*, 509 U.S. at 592-95).

Petitioners assert Dr. Wiznitzer lacked the requisite expertise in “immunology, neuroimmunology, and associated human immunological processes,” and that his identified areas of expertise do not encompass “cellular level processes” or the effects of those processes on auto-immune disorders. Id. at 6-7.

The Court applies an “abuse of discretion” standard of review to a special master’s determinations concerning the reliability of expert testimony. Gen. Elec. Co. v. Joiner, 522 U.S. 136, 142-43 (1997); Terran, 195 F.3d at 1316 (referencing Burns v. Sec’y of Health & Human Servs., 3 F.3d 415, 416-17 (Fed. Cir. 1993)). Consistent with a special master’s findings of fact, the Court is “highly deferential” to a special master’s determinations of expert witness reliability. See Burns, 3 F.3d at 416 (internal quotation omitted).

Here, given the Broekelschen II precedent, the dispositive issue was whether or not Thomas experienced inflammation.⁴ Petitioners explicitly conceded that, as a

⁴ In Lombardi v. Secretary of Health and Human Services, ___ F.3d ___, 2011 WL 3890521, at *14-15 (Fed. Cir. Sep. 6, 2011) (O’Malley, J., concurring), Judge O’Malley observed that:

Broekelschen . . . provides a mechanism for special masters to shortcut the causation analysis in instances where the alleged injuries can support multiple diagnoses. As long as the respondent suggests an alternate diagnosis, the special master can effectively render his own diagnosis and deny compensation without ever shifting the burden to the government. . . . I believe we should revisit or significantly limit our decision in Broekelschen.

The Court notes that, in the absence of Broekelschen II, Petitioners might have succeeded in making a prima facie case, thereby shifting the Althen burden to Respondent. For example, Thomas’s white blood cell and protein levels might have been within the range of “normal” for an adult but suggestive of inflammation in an infant, and Thomas’s thin corpus callosum, as evidenced in the October 19, 1992 MRI, might have been suggestive of vaccine-triggered atrophy. See Steinman, Tr. 62, 331. Nevertheless, the Court must defer because the special master had a reliable basis for his opinion in Thomas’s contemporaneous medical records and in the competing testimony of Dr. Wiznitzer. See Ricci, 2011 WL 2260391, at *12 n.13. The Federal Circuit explained almost a generation ago:

The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is ‘logical’ and legally probable, not medically or scientifically certain. . . . The special masters are not ‘diagnosing’ vaccine-related injuries. . . . Our extremely deferential standard of review as to factual issues in vaccine cases is justified by the notion that these are not appeals from judgments in tort lawsuits, but are appeals in the federal administration of a fund for children shown to have been injured by vaccines.

Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). To the extent that Broekelschen II moves the Court away from the wisdom of Knudsen, it may be frustrating the long-recognized policy of the Vaccine Act to provide a forum for sympathetic litigants like Thomas Ricci.

pediatric neurologist, Dr. Wiznitzer was generally competent to diagnose inflammation. See Wiznitzer, Tr. 206. At a minimum, Dr. Wiznitzer was competent to testify on the manifestations (seizures) of Thomas's immunological issues.

Conclusion

For the foregoing reasons, the special master's May 16, 2011 decision denying compensation is AFFIRMED. This Court finds that the special master did not err in denying Thomas Ricci's claim. Accordingly, Petitioners' motion for review is DENIED.

Pursuant to Rule 18(b) of the Court's Vaccine Rules, the parties may submit any proposed redactions of confidential or other protected information within fourteen days from the date of this opinion before it is released for publication.

IT IS SO ORDERED.

s/Thomas C. Wheeler
THOMAS C. WHEELER
Judge